

PCT

WORLD INTELLECTUAL PROPERTY ORGANIZATION International Bureau



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 7:
A61F 2/44
A2 (43) International Publication Number: WO 00/42954
(43) International Publication Date: 27 July 2000 (27.07.00)

(21) International Application Number: PCT/US00/01766

(22) International Filing Date: 24 January 2000 (24.01.00)

(30) Priority Data:

60/116,852 22 January 1999 (22.01.99) US 09/328,283 8 June 1999 (08.06.99) US

(71) Applicant: OSTEOTECH, INC. [US/US]; 51 James Way, Eatontown, NJ 07724 (US).

(72) Inventors: SCARBOROUGH, Nelson, L.; 47 Lambert Johnson Drive, Ocean, NJ 07712 (US). BOYLE, John, W.; 10 Cornell Way, Upper Montclair, NJ 07043 (US).

(74) Agents: DILWORTH, Peter, G. et al.; Dilworth & Barrese, 333 Earle Ovington Boulevard, Uniondale, NY 11553 (US).

(81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

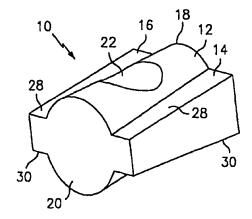
Published

Without international search report and to be republished upon receipt of that report.

(54) Title: INTERVERTEBRAL IMPLANT

(57) Abstract

An intervertebral implant having a composite wedge/dowel configuration is provided. The intervertebral implant includes a central body portion and a pair of radially extending wings. The radially extending wings can be tapered from a first end of the implant to the second end of the implant along an axis parallel to the longitudinal axis of the central body portion. Alternately, the radially extending wings can be tapered along an axis transverse to the longitudinal axis of the cylindrical body portion or along any other axis between parallel and transverse to the longitudinal axis. A throughbore or plurality of throughbores extend from a top surface of the implant through the implant to a bottom surface of the implant. The implant may be formed from a cortical ring cut from the diaphysis of a long bone by milling the top and bottom surfaces of the cortical ring to form the substantially central body portion and the tapered radially extending wings. The corticul ring is milled such that the intramedullary canal of the cortical ring defines a throughbore in the central body portion of the implant. The sidewalls of the implant may be machined to form a



substantially rectangular shape or the implant can be left to have a substantially circular configuration. Alternately, the implant may be formed of any biocompatible material having the requisite strength requirements via any known process, i.e., molding.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain		LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland		LT	Lithuania	SK	Slovakia
AT	Austria	FR -	France		LU	Luxembourg .	SN	Senegal
AU	Australia	GA	Gabon		LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom		MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia		MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana		MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea		MK	The former Yugoslav	TM	Turkmenistan
BF	Burkina Faso	GR	Greece			Republic of Macedonia	TR	Turkey
BG	Bulgaria	HU	Hungary		ML	Mali	TT	Trinidad and Tobago
BJ	Benin	I R	Ireland		MN	Mongolia	UA	Ukrainc
BR	Brazil	IL	Israel		MR	Mauritania	UG	Uganda
BY	Belarus	IS	Iceland		MW	Malawi	US	United States of America
CA	Canada	, IŢ	Italy		MX	Mexico	ÜΖ	Uzbekistan
CF	Central African Republic	JP	Japan		NE	Niger	VN	Viet Nam
CG	Congo	KE	Kenya		NL	Netherlands	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan		NO	Norway	zw	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's		NZ	New Zealand		
CM	Cameroon		Republic of Korea	1	PL	Poland		
CN	China	KR	Republic of Korea		PT	Portugal		
CU	Cuba	К7.	Kazakstan		RO	Romania		
CZ	Czech Republic	LC	Saint Lucia		RU	Russian Federation		
DE	Germany	LI	Licchtenstein		SD	Sudan		
DK	Denmark	LK	Sri Lanka		SE	Sweden		
EE	Estonia	LR	Liberia		SG	Singapore		

Description

10

15

INTERVERTEBRAL IMPLANT

BACKGROUND OF THE INVENTION

5 1. Technical Field

10

15

20

The present disclosure relates generally to intervertebral implants and, more particularly, to an intervertebral implant having a composite wedge/dowel configuration suitable for interbody spinal fusion.

2. Background of Related Art

20

Intervertebral implants for fusing together adjacent vertebrae of a spinal column are well known in the surgical arts. Typically, a surgical procedure for implanting an intervertebral implant between adjacent vertebrae is performed to treat back pain in patients with ruptured or degenerated intervertebral discs, spondylolisthesis or other pathologies. A variety of different types of intervertebral implants have been developed for such a procedure including intervertebral wedge

30

25

implants, spinal fusion cages and cylindrical threaded bone dowels.

35

and stepped bone dowels. Exemplary implants are disclosed in U.S. Patent

40

Applications filed on even date herewith, under Certificate of Express Mail Label Nos.

developed to perform this function including spinal fusion cages, threaded bone dowels

A variety of different types of intervertebral implants have been

45

EL260888076US and EL071686220US, and entitled "Ramp-Shaped Intervertebral Implant" and "Keyed Intervertebral Dowel", respectively, the entire disclosures of

which are incorporated herein by reference.

50

SUBSTITUTE SHEET (RULE 26)

*WO 00/42954 PCT/US00/01766

One fusion cage described in U.S. Patent No. 5,015,247 includes a cylindrical implant constructed from titanium having one closed end, one open end and a series of macro-sized openings formed through a side wall of the implant. The open end of the cylindrical implant is internally threaded and configured to receive a cap. A series of external threads are formed about the circumference of the cylindrical implant. Prior to use, a bone graft of cancellous bone taken from a patient's iliac crest is placed in a press and forced into the hollow body of the cylindrical implant such that cancellous bone extends through the macro-sized openings. The cap is then screwed onto the internally threaded end of the implant. Subsequently, the cylindrical implant is screwed into a previously prepared receiving bed between two adjacent vertebrae.

Because of their simplicity, spinal fusion cages are widely accepted. However, spinal fusion cages suffer from several drawbacks. For example, the cylindrical loading surface area of spinal fusion cages is small, thus two spinal fusion cages are typically required during a surgical procedure. Secondly, spinal fusion cages are made primarily from metal, most notably titanium. This material does not remodel but remains in a patient forever or until it is removed. Since vertebral bodies eventually fuse with the cancellous bone or other bone growth material positioned within the fusion cage, if removal is required, it can be very difficult and dangerous to the patient. Thirdly, spinal fusion cages do not maintain lordosis, thus the natural curvature of the spine is altered. Finally, it is difficult to insert a spinal fusion cage and

·**-2**-

WO 00/42954	PCT/US00/01766
WU 00/42934	FC1/0300/01/00

achieve equal purchase with the adjacent vertebrae. A spinal fusion cage will often tend to engage one vertebrae more securely than the other.

Wedge implants also suffer from several drawbacks. Although wedge implants have a greater load bearing surface area and are configured to maintain lordosis, wedge implants are more difficult to secure in place since they are not threaded into the vertebrae. Moreover, wedge implants have limited ability to prevent rotational forces between the two vertebrae that are intended to be fused.

Threaded bone dowels also suffer from some of the same drawbacks as spinal fusion cages. Threaded bone dowels have a small loading surface area and they do not maintain lordosis. Furthermore, threaded bone dowels are typically cut from bone with a hollow drill bit and subsequently are threaded. The hollow drill bit is positioned to cut transversely through the bone and the intramedullary canal during the cut. If the distance between the outer surface of the cut dowel and the intramedullary canal does not exceed a predetermined thickness, the dowel must be rejected. Since there is little bone to spare during such a transverse cut, a high percentage of bone dowels cut may be rejected due to anatomical variability between donors.

Accordingly, a need exists for an improved intervertebral implant which maintains simplicity for consistent surgical implantation, creates an improved biomechanical construct when implanted, maintains lordosis, conforms to vertebral endplates, spares the endplates in the load bearing region while perforating them in other areas to gain access to cells in cancellous bone; when produced from bone, can

-3-

WO 00/42954 PCT/US00/01766

remodel into bone, can be easily manufactured and addresses other problems associated with current spinal fusion implants.

SUMMARY

In accordance with the present disclosure, an intervertebral implant

having a composite wedge/dowel configuration is provided. The intervertebral implant includes a central body portion and a pair of radially extending wings. The radially extending wings can be tapered from a first end of the implant to the second end of the implant along an axis parallel to the longitudinal axis of the cylindrical body portion for anterior or posterior insertion. Alternately, the radially extending wings can be tapered along an axis perpendicular to the longitudinal axis of the cylindrical body portion for lateral insertion or the wings can be tapered along any axis between axis parallel and perpendicular to the longitudinal axis of the implant. A throughbore or a plurality of throughbores extend from a top surface of the implant to a bottom surface of the implant providing a space for boney bridging to occur between the vertebrae which are intended to be fused. The throughbore(s) is dimensioned to receive growth factors

In a preferred embodiment, the implant is formed from a cortical ring allograft cut from the diaphysis or metaphysis of a long bone. The implant can be formed by milling the top and bottom surfaces of the cortical ring to form the central body portion and the tapered radially extending wings. The implant is milled such that the intramedullary canal of the cortical ring defines a throughbore in the central body

including autograft, allograft, DBM, etc., to stimulate bone healing.

-4-

50

5

10

15

20

25

30

35

40

45

WO 00/42954	PCT/US00/0176
-------------	---------------

5		portion of the implant. Thereafter, the sidewalls of the implant may be machined to
		form a substantially rectangular shape or be maintained in an essentially semi-circula
		configuration. Alternately, the implant may be formed of any biocompatible materia
10		having the requisite strength requirements via any known process, i.e., molding,
	5	casting, machining, etc.
15		BRIEF DESCRIPTION OF THE DRAWINGS
70		Various preferred embodiments are described herein with reference to
		the drawings wherein:
20		FIG. 1 is a perspective view of one embodiment of the presently
	10	disclosed intervertebral implant;
		FIG. 2 is a side view of the intervertebral implant shown in FIG. 1;
25		FIG. 3 is a top view of the intervertebral implant shown in FIG. 1;
		FIG. 4 is a front view of the intervertebral implant shown in FIG. 1;
30		FIG. 5 is a perspective view of another embodiment of the presently
	15	disclosed intervertebral implant;
		FIG. 6 is a side view of the intervertebral implant shown in FIG. 5;
35		FIG. 7 is a top view of the intervertebral implant shown in FIG. 5;
		FIG. 8 is a front view of the intervertebral implant shown in FIG. 5;
40		FIG. 9 is a side view of a long bone;
	20	FIG. 10 is a perspective view of a cortical ring cut from the long bone
		shown in FIG. 9;
45		
		-5-
50		•
- -		

5		FIG. 11 is a side view of the cortical ring shown in FIG. 10;
		FIG. 12 is a perspective view of the cortical ring after the top surface has
		been milled;
10		FIG. 13 is a perspective view of the cortical ring after the bottom surface
	5	has been milled;
15		FIG. 14 is a perspective view of the cortical ring after the sidewalls have
		been machined;
		FIG. 15 is a perspective view of the cortical ring after the radially
20		extending wings have been tapered;
	10	FIG. 16 is a perspective view of a third embodiment of the presently
25		disclosed intervertebral implant;
		FIG. 17 is a perspective view of a fourth embodiment of the presently
		disclosed intervertebral implant;
30		FIG. 18 is a perspective view of a fifth embodiment of the presently
	15	disclosed intervertebral implant;
35		FIG. 18a is a perspective view of a variety of different shaped
55		protrusions;
		FIG. 19 is a perspective view of a sixth embodiment of the presently
40		disclosed intervertebral implant;
	20	FIG. 20 is a front view of the intervertebral implant shown in FIG. 19;
45		FIG. 21 is a top view of the intervertebral implant shown in FIG. 19;
45		
		-6-
50		

WO 00/42954

55

PCT/US00/01766

	WO 00/42954	PCT/US00/01766
5		FIG. 22 is a side view of the intervertebral implant shown in FIG. 19;
		FIG. 23 is a perspective view of a seventh embodiment of the presently
	disclose	ed intervertebral implant;
10		FIG. 24 is a side view of the intervertebral implant shown in FIG. 23;
	5	FIG. 25 is a front view of the intervertebral implant shown in FIG. 23
15		FIG. 26 is a top view of the intervertebral implant shown in FIG. 23;
		FIG. 27 is a perspective view of an eighth embodiment of the presently
	disclose	ed intervertebral implant;
20		FIG. 28 is a side view of the intervertebral implant shown in FIG. 27;
	10	FIG. 29 is a top view of the intervertebral implant shown in FIG. 27;
		FIG. 30 is a side view of the intervertebral implant shown in FIG. 27;
25		FIG. 31 is a top view of a pair of the intervertebral implants shown in
	FIG. 27	in their implanted positions;
30		FIG. 32 is a perspective view of another embodiment of the
	15 interver	tebral implant;
		FIG. 33 is a perspective view of another embodiment of the
35	interver	tebral implant;
		FIG. 34 is a top view of the intervertebral implant shown in FIG. 33;
40		FIG. 35 is a front view of the intervertebral implant shown in FIG. 33;
	20	FIG. 36 is a side view of the intervertebral implant shown in FIG. 33;
45		
		· -7-
50		

WO 00/42954	PCT/US00/0176

5	

FIG. 37 is a front perspective view of another embodiment of the intervertebral implant; and

10

FIG. 38 is a side perspective view of the intervertebral implant shown in

10

5 DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

15

Preferred embodiments of the presently disclosed intervertebral implant will now be described in detail with reference to the drawings, in which like reference numerals designate identical or corresponding elements in each of the several views.

20

FIGS. 1-4 illustrate one preferred embodiment of the presently disclosed

25

intervertebral implant shown generally as 10. Briefly, intervertebral implant 10 includes a substantially cylindrical body portion 12 having a pair of radially extending wings 14 and 16. Cylindrical body portion 12 has a first end 18 and a second end 20.

•-

Each of radially extending wings 14 and 16 has a trapezoidal shape as viewed from the

30

side of intervertebral implant 10.

FIG. 37.

from a top surface 24 of body portion 12 to a bottom surface 26 of body portion 12.

Cylindrical body portion 10 includes a throughbore 22 which extends

_35

Throughbore 22 has a central axis which is perpendicular to the longitudinal axis of

40

radially extending wings 14 and 16 and cylindrical body portion 10. Throughbore 22 is

20

10

15

biocompatible osteoinductive or osteoconductive material. These materials may include

dimensioned to receive bone growth material including bone particles and/or a

45

cancellous bone, cancellous bone particles, ceramics, polymers, composites, BMP, etc.

-8-

50

SUBSTITUTE SHEET (RULE 26)

WO 00/42954 PCT/US00/01766

Although not shown, additional bores may be formed through wings 14 and 16. These bores may also be packed with bone growth material.

5 f

. 20

Radially extending wings 14 and 16 each include an upper surface 28 and a lower surface 30. Surfaces 28 and 30 are tapered to converge toward each other from first end 18 of cylindrical body portion 12 to second end 20 of cylindrical body portion 12, i.e., the height of the wings decreases from the first end to the second end of the implant. The wings are shaped in such a fashion as to conform to the vertebral end plates located above and below the implant. Implant 10 is suitable for anterior and posterior insertion. Alternately, surfaces 28 and 30 may be parallel to each other.

Intervertebral implant 10 can be constructed from a broad range of biocompatible materials, such as surgical stainless steel, titanium, ceramic hydroxyopatite, polymers, carbon fiber tantalum, etc., but is preferably constructed from cadaveric human or animal bone or bone composites. Such composites may include those discussed in U.S. Patent No. 5,899,939 to Boyce et al. and in U.S. Patent Application Serial No. 09/256,447 to Boyce et al., the entire disclosures of which are incorporated herein by reference. Intervertebral implant 10 can be used in cervical, thoracic and lumbar spinal fusion procedures. For cervical spinal fusion procedures, in which implants are typically between 8-15 mm in length and 10-14 mm in diameter, bone is preferably obtained from the fibula, radius, ulna or humerus. For thoracic and lumbar spinal fusion procedures in which implants are typically 10-30 mm in diameter and about 14-20 mm in height, bone is preferably obtained from the humerus, femur or

-9-

	PCT/US00/01766
WO 00/42954	PC1/USUU/01/06

	W	O 00/42954		PCT/US00/01766
5		fashion, only the walls of the int	ramedullary canal and the circumfe	erential surfaces of
		the bone may be demineralized.	The strength imparting surfaces o	f the radially
		extending wings and the radial s	urface of the implant will not be co	ompromised.
10		Moreover, the bone may be treat	ted using a variety of bone healing	enhancing
	5	technologies. For example, bon	e growth factors may be infused in	to the natural
15		porosity of the bone and/or the b	oone may be infused with acid to fu	rther demineralize
		the bone. Both these bone treatr	nents may be performed using the	pressure flow system
		disclosed in U.S. Patent No. 5,8	46,484 which is incorporated here	in by reference.
20		As discussed above	ve, intervertebral implant 10 need i	not be formed from
-	10	human cadaveric or animal bone	but rather may be formed from an	y biocompatible
		material. As such, other known	processes, such as molding, casting	g or machining
25		techniques, may be used to many	ufacture the implant.	
		FIGS. 5-8 illustra	te another embodiment of the inter	vertebral implant
30		shown generally as 100. Interve	ertebral implant 100 is similar to in	tervertebral implant
	15	10 in that it includes a cylindrica	al body portion 112, a pair of radia	lly extending wings
		114 and 116 and a throughbore	122 having a central axis which is	perpendicular to the
35		longitudinal axis of the radially	extending wings and cylindrical bo	dy portion.
		However, radially extending win	ngs 114 and 116 are tapered transv	ersely such that wing
40		116 has greater height than wing	g 114. Implant 100 is suitable for	ateral intervertebral
	20	inantian		

50

55

-11-

VO 00/42954	PCT/US00/01766
NO 00/42934	1 C1/0300/01/00

	wo	0 00/42954 PCT/US00/01766 Intervertebral implant 100 may be manufactured using the same
5		procedure as discussed above with respect to intervertebral implant 10 with slight
		variation in the milling step for forming the taper on the radially extending wings.
10		Alternately, intervertebral implant 100 may be formed from a biocompatible material
	5	having the requisite strength requirements via any known process, i.e., molding,
15		casting or machining.
,,		Referring to FIGS. 16-18, intervertebral implants 10 and 100 may
		include retaining structure for preventing the implant from migrating from an implanted
20		position after implantation. For example, intervertebral implant 200 (FIG. 16) includes
	10	a plurality of triangular protrusions 202 formed on the tapered surfaces of the radially
		extending wings. Protrusions 202 engage the adjoining vertebrae and prevent the
25		implant from movement in relation thereto. Alternately, the protrusions may assume a

15 Perforations (not shown) for receiving bone growth material may also be provided on the outer surface of the implant. It is noted that such protrusions or perforations may also be provided on the cylindrical body portion of the intervertebral implant.

17) or spherically-shaped protrusions 206 (FIG. 18) may also be provided.

variety of different configurations. For example, ridge-shaped protrusions 204 (FIG.

FIG. 18a illustrates a variety of different protrusions which may be formed anywhere on the implant to prevent the implant from migrating from its implanted position in the intervertebral space.

45

30

35

40

20

-12-

WO 00/42954	PCT/US00/01766

5	

intervertebral implant shown generally as 300. Intervertebral implant 300 includes a substantially cylindrical body portion 312 having a pair of radially extending wings 314 and 316. Radially extending wings 314 and 316 have a substantially semi-circular shape and have a height which decreases from a first end to a second end of the implant. A series of holes 320 are formed in wing 316 and a throughbore 322 extends through cylindrical body portion 312. Each of holes 320 and throughbore 322 is configured to receive bone growth material, as discussed above. Alternately, holes 320 may be formed in both radially extending wings 314 and 316.

FIGS. 19-22 illustrate an alternate embodiment of the presently disclosed

Referring to FIGS. 23-26, the intervertebral implant, shown generally as 400, may include a substantially conical body portion 412. See also FIGS. 16-18. Conical body portion 412 decreases in height from first end 418 to second end 420 of the implant.

Referring to FIGS. 27-31, the intervertebral implant, shown generally as 500, may include only one radially extending wing 514. The other radially extending wing 516 can be either partially or completely eliminated. As illustrated in FIGS. 27-30, radially extending wing 516 has been truncated. During a surgical procedure in which two intervertebral implants are implanted between adjoining vertebrae, the side of each implant having the truncated wing (or the side from which the implant has been eliminated) is positioned adjacent to the truncated wing of the other implant. See FIG. 31.

-13-

VO 00/42954	PCT/US00/0176

FIG. 32 illustrates another embodiment of the intervertebral implant shown generally as 600. Intervertebral implant 600 includes a pair of cylindrical body portions 612a and 612b, a pair of radially extending wings 614 and 616, a central body portion 618 and a throughbore 622. Throughbore 622 is centrally located in implant 600 and extends through a portion of both cylindrical body portions 612a and 612b. A single implant 600 can be used in surgical procedures which typically required two intervertebral implants such as that shown in FIG. 31.

FIGS. 33-36 illustrate another embodiment of the intervertebral implant shown generally as 700. Implant 700 includes a substantially cylindrical body portion 712 having a pair of radially extending semi-circular wings 714 and a throughbore 722. The top and bottom surfaces 724 and 726 of wings 714 are convex to conform to the anatomical shape of the vertebral end plates. Alternately, the top and bottom surfaces of the wings may assume other shapes which conform to the shape of the vertebral endplates. Implant 700 further includes a slot 750 and a threaded bore 752. Threaded bore 752 extends from slot 750 into throughbore 722. Slot 750 and threaded bore 752 are configured to engage an implant insertion tool (not shown) to facilitate insertion of the implant into the intervertebral space. Although the slot and threaded bore are not shown in combination with the other implants disclosed in this application, it is contemplated that each of the implants disclosed herein may include such insertion tool engaging structure.

-14-

NO 00/42954	PCT/US00/01766
W(1) ()(I)/4/954	1 € 17 € 50 € 70 €

5	
_	

It will be understood that various modifications may be made to the embodiments disclosed herein. For example, radially extending wings have been described as being tapered or angled along axis both parallel and transverse to the longitudinal axis of the implant. Alternately, radially extending wings can be tapered along any axis between the parallel and transverse axis. For example, radially extending wings 814 of implant 800 are tapered along an axis which forms an angle of about 45° with respect to the longitudinal axis of the cylindrical body portion 812. See FIGS. 37 and 38. Moreover, the taper of the radially extending wings may be different than that shown but should be such as to maintain the natural alignment of the vertebrae. Alternately, radially extending wings need not be tapered. Therefore, the above description should not be construed as limiting, but merely as exemplifications of preferred embodiments. Those skilled in the art will envision other modifications within the scope and spirit of the claims appended hereto.

-15-

Claims

·wo	00/4295	4

PCT/US00/01766

<u>WHA</u>	T	IS	CL	ΑI	М	ED	IS	:

1. An intervertebral implant comprising: a first central body portion having a longitudinal axis; and at least one wing extending radially outwardly from the central body

5 portion.

10

15

2. An intervertebral implant according to claim 1, wherein the at least one radially extending wing has a height which decreases along the longitudinal axis of the cylindrical body portion from one end of the cylindrical body portion to the other end of the cylindrical body portion.

3. An intervertebral implant according to claim 2, wherein the intervertebral implant includes two radially extending wings, each of the radially extending wings having a shape substantially the same as the other radially extending wing.

4. An intervertebral implant according to claim 1, wherein the at least one radially extending wing has a height which decreases in a direction perpendicular to the longitudinal axis of the cylindrical body portion.

-16-

20

45

5

10

15

20

25

30

35

40

50

SUBSTITUTE SHEET (RULE 26)

WO 00/42954	PCT/US00/0176
11 0 00/12/27	

5		5. An intervertebral implant according to claim 4, wherein the
		intervertebral implant includes a pair of radially extending wings, wherein the smallest
		height of one of the radially extending wings being greater than the largest height of the
10		other of the radially extending wings.
	5	·
15		6. An intervertebral implant according to claim 1, wherein the implant
		is manufactured from bone.
20		7. An intervertebral implant according to claim 6, wherein the implant
	10	is manufactured from the diaphysis or the metaphysis of a long bone.
25		8. An intervertebral implant according to claim 7, wherein the
		intramedullary canal of the long bone defines the throughbore.
30		
	15	9. An intervertebral implant according to claim 1, wherein the implant
		is manufactured from a cortical ring cut from the diaphysis or metaphysis of a long
35		bone.
40		10. An intervertebral implant according to claim 1, wherein the implant
40	20	is manufactured from a biocompatible material.
45		,
		-17-
50		•
50		

WO 00/42954	PCT/US00/01766

5		11. An intervertebral implant according to claim 1, further including
		protrusions formed on the surface of the intervertebral implant.
10		12. An intervertebral implant according to claim 11, wherein the
	5	protrusions are formed on the at least one radially extending wing.
15		
		13. An intervertebral implant according to claim 1, wherein the implant
		is formed from a bone derived composite material.
20		
	10	14. An intervertebral implant according to claim 1, wherein the implant
25		is formed from a bone derived layered material.
		15. An intervertebral implant according to claim 1, further including at
30		least one opening formed in the at least one radially extending wing.
	. 15	
		16. An intervertebral implant according to claim 1, further including at
35		least one throughbore defined in the central body portion, the throughbore having an
		axis which is substantially perpendicular to the longitudinal axis of the substantially
40		cylindrical body portion.
	20	
45	•	
		10
		-18-
50		
55		SUBSTITUTE SHEET (RULE 26)

WO 00/42954	PCT/US00/01766
-------------	----------------

5		17. An intervertebral implant according to claim 1, further including a
		second central body portion having a longitudinal axis.
10		18. An intervertebral implant according to claim 17, wherein the first
	5	and second central body portions have parallel longitudinal axis.
15		
		19. An intervertebral implant according to claim 18, wherein the at least
		one radially extending wing includes two radially extending wings, one of the two
20		radially extending wings extending outwardly from each of the first and second central
	10	body portions.
25		20. An intervertebral implant according to claim 1, wherein the at least
		one radially extending wing includes two radially extending wings.
30		
	15	21. An intervertebral implant according to claim 20, wherein each of the
		radially extending wings includes a top and a bottom surface, the top and bottom
35		surfaces being shaped to conform to the shape of vertebral endplates.
		22. An intervertebral implant according to claim 22, wherein at least
40	20	one of the top and bottom surfaces of the radially extending wings is convex.
45		
		-19-
50		
55		SUBSTITUTE SHEET (RULE 26)

WO 00/42954	PCT/US00/01766
110 00/42/54	

23. An intervertebral implant according to claim 1, further including

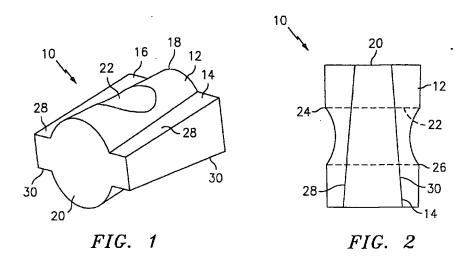
		engaging structure formed on the implant, the engaging structure being configured to
		receive an end of an implant insertion tool.
10		·
	5	24. A method for forming an intervertebral implant from the diaphysis
15		or metaphysis of a long bone comprising the following steps:
		a. making a transverse cut across a long bone to form a cortical ring;
		b. milling the top surface of the cortical ring to form a first
20		longitudinally extending crown having two upper radially extending flats; and
	10	c. milling the bottom surface of the cortical ring to form a second
25		longitudinally extending crown having two lower radially extending flats, the upper and
25		lower flats forming a pair of radially extending wings.
**		
30		25. A method according to claim 24, wherein the first and second
	15	crowns are milled to form a substantially cylindrical body portion.
<u>.</u> 35		26. A method according to claim 25, wherein the first and second
		crowns are milled such that the intramedullary canal of the long bone extends through
40		the substantially cylindrical body portion.
	20	
		27. A method according to claim 26, further including the steps of:
45		
		-20-
50		
55		SUBSTITUTE SHEET (RULE 26)

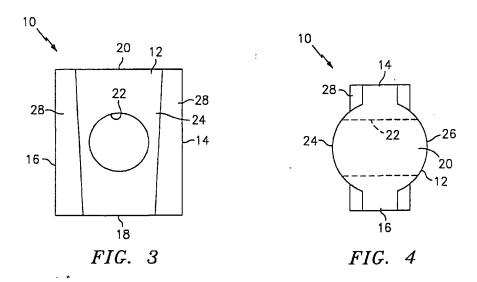
wo	00/42954
----	----------

PCT/U	SUU/	U1	7	ы
-------	------	----	---	---

5	milling the side surfaces of the cortical ring to form a substantially
	rectangular implant.
5	28. A method according to claim 25, further including the step of milling the upper and lower radially extending flats to vary the angle of the flats in
15	direction parallel to the longitudinally extending axis of the substantially cylindrical body portion.
20	29. A method according to claim 25, further including the step of
10	milling the upper and lower radially extending flats to vary the angle of the flats in
25	direction transverse to the longitudinal axis of the cylindrical body portion.
30	30. A method according to claim 24, further including the following
15	d. forming protrusions on the intervertebral implant.
35	31. A method according to claim 30, wherein the protrusions are
	formed on the radially extending wings.
40	32. A method according to claim 24, wherein the first and second
45	crowns are milled to form a substantially conical body portion.
	-21-
50	

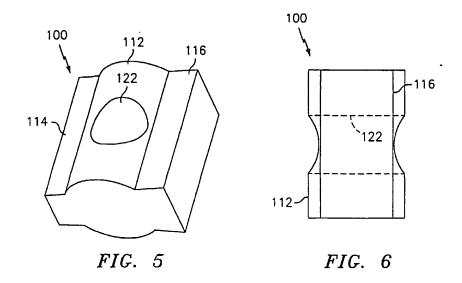
5	33. A method according to claim 24, further including the step of forming at least one hole in at least one of the radially extending wings.
10	34. A method according to claim 24, wherein at least one of the upper5 and lower flats defining each of the radially extending wings is convex.
15	
20	
25	
30	•
35	
40	
45	-22-
50	

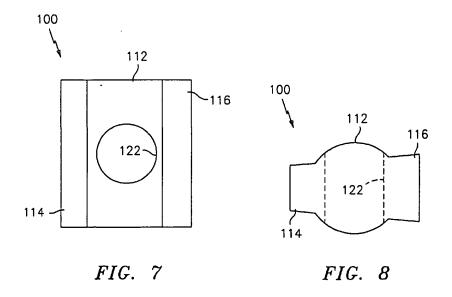


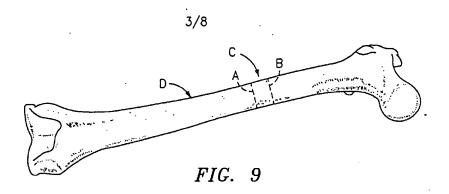


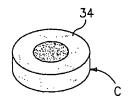
SUBSTITUTE SHEET (RULE 26)

2/8









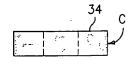
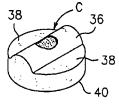


FIG. 10

FIG. 11



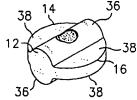
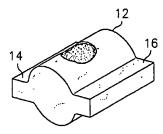


FIG. 12

FIG. 13



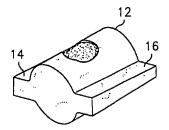
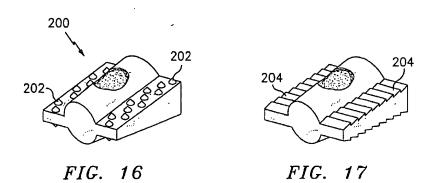


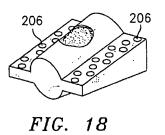
FIG. 14

FIG. 15

WO 00/42954 PCT/US00/01766

4/8





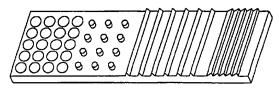
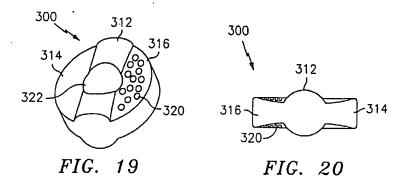
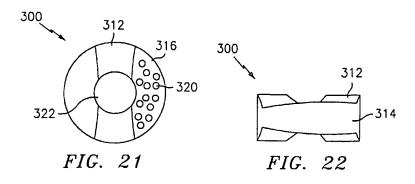
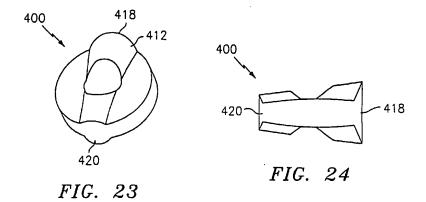


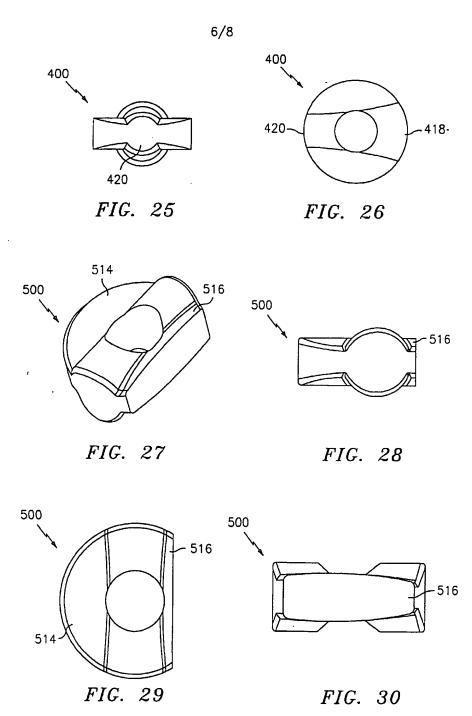
FIG. 18α



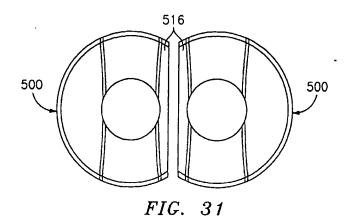


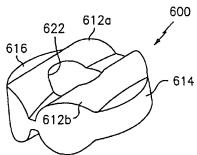


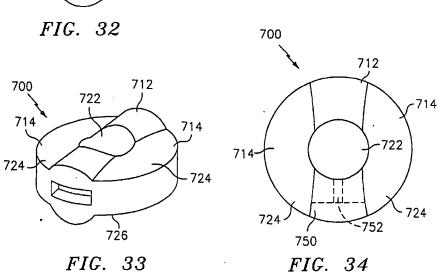
SUBSTITUTE SHEET (RULE 26)

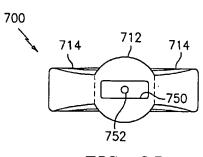


SUBSTITUTE SHEET (RULE 26)









712 726 714 750 722 726 722 FIG. 36

FIG. 35

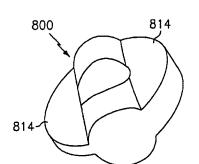


FIG. 37

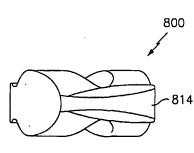


FIG. 38